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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/595,378	11/27/2006	David Keith James	305832-01003	8440

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EXAMINER	
LAVERT, NICOLE F	
ART UNIT	PAPER NUMBER
3762	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/595,378	JAMES ET AL.	
	Examiner	Art Unit	
	NICOLE F. LAVERT	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 September 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-39* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *29 February 2008* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/5/09, 6/13/08, 1/30/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In regards to independent claims 1 & 22, it is unclear as to what is being claimed due to the claim limitations "…by use of…" or "…by at least one technique..." since the claims do not state that these functions are being performed, i.e., it is unclear if the claim limitations are active method step recitations or structural recitations.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

1. **Claims 1-10, 18-29 & 37-38** are rejected under 35 U.S.C. 103 (a) as being unpatentable over Oriol et al. (US 2001/0014776) in view of Nagel (US 4,211,237).

Oriol et al. discloses an apparatus (e.g., element 10) and a method for monitoring fetal behaviour {e.g., [0005] & (Figs 8 & 13)} comprising; an input for receiving ECG data; a waveform pre-processor (e.g., element 14) for identifying a succession of fetal ECG complex waveforms within the received data (e.g., [0019]-[0020]); a waveform processor (e.g., element 16) for determining differences in the shapes of a succession of fetal ECG complex waveforms over time (e.g., via disclosed 'fetal assessment process') by at least one of the techniques of matching the ECG complex waveforms to a plurality of templates, phase detection and integration [e.g., 0131]; and an event logger determining from the determined differences a number of fetal body movements (e.g., via disclosed 'fetal movement analyzer', element 36) during the period of time (e.g., [0081]-[0082], [0094] & [0102]-[0103]). Note that the Examiner is interpreting the discloses trend variables, in which include data received over a period of time, and are further represented as trend plots on a ECG monitor as being the technique-means used to match fetal ECG complex waveforms to a plurality of templates, as is instantly claimed, used in order to facilitate the assessment of fetal states by reviewing data and evaluating said data by measuring and/or comparing the data against specific, fetal patterns [e.g., 0131].

Oriol et al. discloses the claimed invention having an apparatus and a method for monitoring fetal behaviour comprising an input for receiving ECG data except wherein said ECG

data is from a set of electrodes adapted to be attached to a maternal abdomen positioned at different locations. Nagel teaches that it is known to use a method for identifying occurring signals that are part of a signal mixture, i.e. identifying fetal QRS complexes from a maternal-fetal signal mixture, in which said fetal signals are subtracted from maternal signals, wherein said signals are received from various electrodes (e.g., elements 301-303) fastened to the body of a female patient [e.g., (col 9, ln 62-68), (col 10, ln 1-4) & (Fig 2)]. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the apparatus and method as taught by Oriol et al. with the various electrodes disposed on a female patient used to receive both fetal and maternal ECG signals as taught by Nagel et al., since such a modification would provide the apparatus and a method for monitoring fetal behaviour comprising an input for receiving ECG data from a set of electrodes adapted to be attached to a maternal abdomen positioned at different locations for providing the predictable results pertaining to receiving and/or recording fetomaternal EKG signals via multiple electrodes displaced on a mother's body in order to receive signal to determine the ECG of a fetus [e.g., Nagel, (col 9, ln 62-68), (col 10, ln 1-4) & (Fig 2)].

2. **Claims 12-14 & 31-33** are rejected under 35 U.S.C. 103 (a) as being unpatentable over Oriol et al. (US 2001/0014776) and Nagel (US 4,211,237), as applied to claims 1-3, 6-10, 18-23, 26-29 & 37-38 above, and further in view Beach et al. (US 5,088,498).

Oriol et al./Nagel disclose the claimed invention having an apparatus and a method for monitoring fetal behaviour comprising a waveform pre-processor for detecting phase changes between successive fetal ECG complex waveforms. Beach et al. teaches that it is known to use a phase detector, which determines the approximate phases for ultrasounds reflected at each of

several different depths (e.g., col 4, lines 5-11). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method and apparatus as taught by Oriol et al./Nagel with the phase detector as taught by Beach et al., since such a modification would provide the method and an apparatus for monitoring fetal behavior with a processing means for detecting phase changes between successive fetal ECG complex waveforms for providing the predictable results pertaining to a providing a precise indication for the distance traveled by the reflective tissue of a fetus (e.g., Beach, col 4, lines 10-11).

3. **Claims 15-17, 20, 34-36 & 39** are rejected under 35 U.S.C. 103 (a) as being unpatentable over Oriol et al. (US 2001/0014776) and Nagel (US 4,211,237), as applied to claims 1-3, 6-10, 18-23, 26-29 & 37-38 above, and further in view Oriol et al. (US 5,596,993).

Oriol et al./Nagel disclose the claimed invention having an apparatus and a method for monitoring fetal behaviour comprising a waveform pre-processor that determines a difference in fetal complex waveforms except wherein said pre-processor determines said difference in fetal complex waveforms by detecting a change in the positive and/ or negative energy of the fetal ECG complex waveform relative to a reference wherein an alarm is associated with said monitored fetal behavior. Oriol et al. teaches that it is known to use a time plot of the baseline heart rate signal, in which the plot shows decelerations associated with loss of variability [e.g., (col 9, lines 60-67) & (Figure 5A)]. It would have been obvious to one of ordinary skill in the art at the time of the invention was made to have incorporated Oriol et al./Nagel with the use of a time plot-representation of the baseline heart rate signal, in which the plot shows decelerations associated with loss of variability and a monitoring system as taught by Oriol et al., thereby detecting differences in the fetal complex waveforms by change in the positive and or negative

energy of the fetal ECG complex waveform relative to a reference, since such a modification would provide the method and an apparatus for monitoring fetal behavior by determining a difference in fetal complex waveforms in which the differences in fetal complex waveforms are detected by change in the positive and/ or negative energy of the fetal ECG complex waveform relative to a reference for providing the predictable results pertaining to showing the appearance and temporal relations to contractions of a heart rate signal so that a physician can evaluate a newborn's heart rate, and in order to provide output data, such as warnings and recommendation, to the clinician [e.g., Oriol, (col 9, ln 40-42 & 63-67) & (col 19, lines 39-40 & 54-56)].

Response to Arguments

1. Applicant's arguments with respect to claims 1-39 have been considered but are moot in view of the new ground(s) of rejection as necessitated by amendments.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NICOLE F. LAVERT whose telephone number is (571)270-5040. The examiner can normally be reached on M-F 7:30-5:00p.m. (alt. fridays).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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